

ATTORNEY'S DOCKET NO: M0656/7070(HCL)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Liu et al.  
Serial No: 09/982,548  
Filed: October 18, 2001  
For: METHODS AND PRODUCTS RELATED TO PULMONARY  
DELIVERY OF POLYSACCHARIDES  
Examiner: Unassigned  
Art Unit: 1623

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STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing date of a National Application.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
M0656/7046	09/384,959	08/27/99	Sasisekharan et al.
M0656/7055	09/557,997	04/24/00	Venkataraman et al.
M0656/7056	09/558,137	04/24/00	Venkataraman et al.
M0656/7063	09/802,285	03/08/01	Liu et al.
M0656/7069	09/951,138	09/12/01	Sasisekharan et al.

The following are remarks concerning the other information cited:

PART III: Remarks

Documents cited on the attached form PTO-1449 (modified) are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Liu et al.*, Applicant(s)

By:

  
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Docket No. M0656/7070(HCL)

Dated: January 17, 2002

**X01/18/01**



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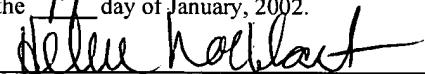
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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WASHINGTON, D.C. 20231

Sir:

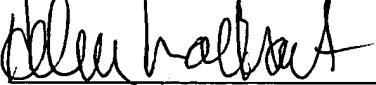
Transmitted herewith is/are the following document(s):

[x] Information Disclosure Statement  
[x] Form PTO1449 with Cited References  
[x] Certificate of Mailing  
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If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No check is enclosed. If a fee is required, the balance may be charged to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,

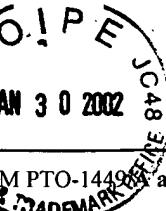


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PCT/US PTM PTO-1449A and B (Modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

APPLICATION NO.: 09/982,548

ATTY. DOCKET NO.: M0656/7070

FILING DATE: October 18, 2001

APPLICANT: Liu et al.

GROUP ART UNIT: 1623

EXAMINER: Unassigned

## U.S. PATENT DOCUMENTS

Examiner's Initials#	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
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#### FOREIGN PATENT DOCUMENTS

Examiner's Initials#	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	EP	0 433 225	A1	CIBA-GEIGY AG	06/19/1991	
	B2	WO	93/08289	A1	Massachusetts Institute of Technology	04/29/1993	
	B3	EP	0 557 887	A2	OPOCRIN S.p.A.	09/01/1993	
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#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials#	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	ALDERMAN, C.P. et al., "Continuous Subcutaneous Heparin Infusion for Treatment of Troussseau's Syndrome", <i>The Annals of Pharmacotherapy</i> , July/August 1995, Pages 710-713, Vol. 29	
	C2	BERNSTEIN, H. et al., "Immobilized Heparin Lyase System for Blood Deheparinization", <i>Methods in Enzymology</i> , 1988, Pages 515-529, Vol. 137, Academic Press, Inc.	
	C3	CARDIN, A.D. et al., "Molecular Modeling of Protein-Glycosaminoglycan Interactions", <i>Arteriosclerosis</i> , January/February 1989, Pages 21-32, Vol. 9, No. 1	
	C4	COMFORT, A.R. et al., "Immobilized Enzyme Cellulose Hollow Fibers: III. Physical Properties and <i>In Vitro</i> Biocompatibility", <i>Biotechnology and Bioengineering</i> , 1989, Pages 1383-1390, Vol. 34, John Wiley & Sons, Inc.	
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	C7	ENRIQUEZ-HARRIS, P. et al., "Growth factors and the extracellular matrix", <i>Meeting Report, Trends in Cell Biology</i> , 1994, 2 Pages	
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	C14	HART, G.W., "Glycosylation", <i>Current Opinion in Cell Biology</i> , 1992, Pages 1017-1023, Vol. 4		
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	C17	KAKKAR, A.K. et al., "Venous thromboembolism and cancer", <i>Baillier's Clinical Haematology</i> , September 1998, Pages 675-687, Vol. 11, No. 3, Bailliere Tindall		
	C18	KANABROCKI, E.L. et al., "Heparin as a Therapy for Atherosclerosis: Preliminary Observations on the Intrapulmonary Administration of Low-Dose Heparin in the Morning Versus Evening Gauged by Its Effect on Blood Variables", <i>Chronobiology International</i> , 1991, Pages 210-233, Vol. 8, No. 3, International Society of Chronobiology		
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	C20	KRETSINGER, R.H. et al., "Structure and Evolution of Calcium-Modulated Proteins", <i>CRC Critical Reviews in Biochemistry</i> , July 1980, Pages 119-174, Vol. 8, No. 2		
	C21	LECKBAND, D. et al., "An Approach for the Stable Immobilization of Proteins", <i>Biotechnology and Bioengineering</i> , 1991, Pages 227-237, Vol. 37, John Wiley & Sons, Inc.		
	C22	LINHARDT, R.J. et al., "Polysaccharide Lyases", <i>Applied Biochemistry and Biotechnology</i> , 1986, Pages 135-176, Vol. 12		
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	C24	LINHARDT, R.J. et al., "Production and Chemical Processing of Low Molecular Weight Heparins", <i>Seminars in Thrombosis and Hemostasis</i> , 1999, Pages 5-16, Vol. 25, Suppl. No. 3, Thiemo Medical Publishers, Inc.		
	C25	LIU, D. et al., "The Calcium-binding Sites of Heparinase I from <i>Flavobacterium heparinum</i> are Essential for Enzymatic Activity", <i>The Journal of Biological Chemistry</i> , February 12, 1999, Pages 4089-4095, Vol. 274, No. 7, The American Society for Biochemistry and Molecular Biology, Inc.		
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	C27	LOHSE, D.L. et al., "Purification and Characterization of Heparin Lyases from <i>Flavobacterium heparinum</i> ", <i>The Journal of Biological Chemistry</i> , December 5, 1992, Pages 24347-24355, Vol. 267, No. 34, The American Society for Biochemistry and Molecular Biology, Inc.		
	C28	LUSTIG, F. et al., "Alternative Splicing Determines the Binding of Platelet-Derived Growth Factor (PDGF-AA) to Glycosaminoglycans", <i>Biochemistry</i> , 1996, Pages 12077-12085, Vol. 35, No. 37, American Chemical Society		
	C29	POJASEK, K. et al., "Histidine 295 and histidine 510 are crucial for the enzymatic degradation of heparan sulfate by heparinase III", <i>Biochemistry</i> , April 11, 2000, Pages 4012-4019, Vol. 39, No. 14, American Chemistry Society		
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	C32	SASISEKHARAN, R. et al., "Cloning and expression of heparinase I gene from <i>Flavobacterium heparinum</i> ", <i>Proc. Natl. Acad. Sci. USA</i> , April 1993, Pages 3660-3664, Vol. 90, Applied Biological Sciences		



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C37	SHRIVER, Z. et al., "Heparinase II from <i>Flavobacterium heparinum</i> , Role of Histidine Residues in Enzymatic Activity as Probed by Chemical Modification and Site-Directed Mutagenesis", <i>The Journal of Biological Chemistry</i> , April 24, 1998, Pages 10160-10167, Vol. 273, No. 17, The American Society for Biochemistry and Molecular Biology, Inc.	TECH CENTER 1600/2900
C38	SHRIVER, Z. et al., "Heparinase II from <i>Flavobacterium heparinum</i> , Role of cysteine in Enzymatic Activity as Probed by Chemical Modification and Site-Directed Mutagenesis", <i>The Journal of Biological Chemistry</i> , September 4, 1998, Pages 22904-22912, Vol. 273, No. 36, The American Society for Biochemistry and Molecular Biology, Inc.	TECH CENTER 1600/2900
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C40	SHRIVER, Z. et al., "Sequencing of 3-O sulfate containing heparin decasaccharides with a partial antithrombin III binding site", <i>Proc. Natl. Acad. Sci. USA</i> , September 12, 2000, Pages 10359-10364, Vol. 97, No. 19	TECH CENTER 1600/2900
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EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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